(ii) sonicating the suspended lymphocytes; and

(iii) filtering the sonicated lymphocytes to obtain the lysate; and

(e) administering the lysate to the individual by:

(i) determining a therapeutic dose of the lysate by skin testing; and

(ii) injecting the individual subcutaneously with the therapeutic dose of the lysate.

61. The method according to Claim 60, wherein the cell growth medium is supplemented with bovine calf serum.

62. The method according to Claim 60, wherein the culture is monitored until the yield is approximately 5-8 x 10^6 cells per ml.

63. The method according to Claim 60, wherein the step of administering the lysate to the individual further comprises the step of: subsequently injecting the individual subcutaneously with at least one additional therapeutic dose of the lysate.

64. The method according to Claim 60, further comprising the steps of: measuring the clinical symptoms and signs of the individual before administering the lysate, and then measuring clinical symptoms and signs of the individual after administering the lysate.

REMARKS

The Applicant's appreciate the Examiner's continued attention to this CPA application.

Claims 49-64 are pending in the application. Dependent Claim 51 has been amended to clarify that which the applicant regards as the invention, and is fully supported by the disclosure at pages 8-10 of the originally-filed specification. New Claims 60-64 are presented to further clarify that which the applicant regards as the invention. No new matter has been added.

A new declaration in compliance with 37 C.F.R. §1.67(a) is being submitted even date herewith with respect to the prior application , which (a) claims priority to International application Serial No. PCT/US96/01205 under 35 U.S.C. § 120, (b) claims priority to U.S. application Serial No. 08/380,063 under 35 U.S.C. § 120; and (c) acknowledges the Applicant's duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 C.F.R. 1.56 which occurred between the filing date of the prior application and the nation or PCT international filing date of the continuation-in-part application.

To avoid any unintended question of adding new matter, the prior cancellation of the word "normal" has been reversed. The word "normal" as used in this application does not create any ambiguity to a person of skill in the art. For example, the types of cells obtained according to the disclosed methodology for preparing an "autogenous lymphocytic factor" ("ALF") derived from a blood sample of the individual as described in the most preferred embodiment at pages 8-10 of the originally-filed specification make the meaning clear. A person of ordinary skill in the art would recognize from the disclosure in this application and background knowledge in the field that even an immunologically-challenged or otherwise sick individual would have at least some "normal" lymphocytic cells in his or her blood, and that large numbers of "normal" or "robust" lymphocytic cells can be propagated from the person's blood sample when the cells are cultured outside the person's immunologically-compromised body. Specification, page 15, lines 14-18. Under culturing conditions such as those described in the application, "normal" lymphocytic cells will propagate in favor of "unhealthy" or "dysfunctional" cells. The method disclosed in the application is clear to a person of skill in the art.

Claims 49-59 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which not was described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed for the following two reasons.

First, it is true that the pending claims do not require that "normal" lymphocytic cells be somehow isolated from "abnormal" lymphocytic cells before the propagation step. As discussed above, neither does the written specification. The disclosure teaches isolating portions of a blood sample containing T and B lymphocytes, including, for example, by way of using a sodium diatrizoate and polysucrose density gradient technique to obtain a lymphocytic sample. Such a technique will provide a sample of "normal" lymphocytes, but not necessarily to the exclusion of any "abnormal" or "dysfunctional" lymphocytes that may be in the blood of an immunologically-challenged person. Propagation of the isolated lymphocytic sample, however, will favor a yield of a large number of "robust" lymphocytic cells. Specification, page 15, lines 14-18. For this reason, the rejection is not understood and is respectfully traversed.

Second, it is true that the pending claims do not require all the details of the specific example disclosed at pages 9-10 of the application. Nevertheless, the disclosure is adequate to support the inventive idea as claimed in broadest pending Claim 49, that being a method for treating a chemically sensitive individual including the following major steps:

(a) collecting a blood sample from the individual;

(b) isolating mixed T and B lymphocytes from the blood sample;

(c) propagating the isolated mixed T and B lymphocytes to obtain propagated lymphocytes;

(d) lysing the propagated lymphocytes to obtain a lysate; and

(e) administering the lysate to the individual.

The scope of this claim is fully supported by the broad statements of the method in the application, including, for example, at page 3, lines 7-24, at page 6, lines 7-11, at page 8, lines 20-24, and at page 15, lines 14-18 of the originally-filed specification. The specification then goes on to disclose the best mode known to the Applicant's at the time the application was filed for practicing these steps of the invention. It is unreasonable to restrict the invention to only the best mode disclosed in the application when the originally-filed specification (and the originally-filed claims) disclose and support a broader scope of the invention. Furthermore, persons of skill in the art would readily be able to appreciate from the disclosure that the major steps involved in the invention can be defined at least as broadly as by the method of Claim 49, and can appreciate modifications that could be made to the most preferred embodiment specifically disclosed in the application. For this reason, the rejection is respectfully traversed.

Claims 49-59 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed. More particularly, the term "chemically sensitive individual" does have a widely accepted meaning in the medical community. An information disclosure statement is filed herewith, for the purposes of providing examples in the record, including: (a) the "Practice Guidelines" of the Pan American Allergy Society revised July 15, 1994; (b) the "Practice Guidelines" of the American Academy of Environmental Medicine published in 1992; (c) excerpts from the four-volume treatise on the subject of "Chemical Sensitivity" by one of the named inventors, Dr. Rea, published by CRC Press in 1994, 1995, and 1997, specifically, Volume 4, pages 7-16; and (d) the "33rd Annual Meeting of the American Academy of Environmental Medicine" held November 8, 1998, including presentations on the topic by Dr. Rea and other physicians. The National Center for Health Statistics has assigned "hypersensitivity" code "995.3", which has been in the classification and the index for over 50 years. Furthermore, as clinically described in these representative examples, the term is generally understood to refer to physical maladies versus psychological manifestations. In addition, the data presented in support of this invention includes objective clinical factors such as: T and B lymphocyte parameters, cell mediated immunity using seven different antigens, complete blood count, standard blood chemistry tests, and scales of clinical symptoms and signs.

Finally, Claims 49-59 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Youdim et al. in view of Warren (U.S. Patent No. 4,435,384). This rejection is respectfully

traversed. Youdim et al. do not teach that its "transfer factor" was produced from autologous blood cells. Warren teaches, among other things, that the donor of the cell sample can have no history of recurrent infection by herpes virus. The very fact that Warren teaches such a limitation on the selection of the donor for the cell sample makes it plain that Warren does not teach or suggest that the blood donor is contemplated to be the same as the patient. Although Warren does not say why, that limitation is apparently designed to protect the patient from infection by the herpes virus. Neither Youdim et al. nor Warren, separately or in combination, teach or disclose the advantage of using autogenous blood cells, including that the patient need not be exposed to risk of infectious disease from a donor, and does not offer the autogenous benefits disclosed by the application, such as less likelihood of rejection. See, e.g., the specification at page 10, lines 8-10.

Reconsideration of the application is respectfully requested. Claims 49-64 are believed to be in condition for allowance, and such action is respectfully requested. If a telephone interview would expedite the prosecution of this application, the undersigned would appreciate a call at the number below.

DATED: December 20, 1999

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